



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,749	03/30/2004	Dominique Charmot	29329-715.201	7226

56631 7590 11/01/2006

WILSON SONSINI GOODRICH AND ROSATI / ILYPSA, INC.
650 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
----------	--------------

1618

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/814,749	Applicant(s) CHARMOT ET AL.	
	Examiner Micah-Paul Young	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,14,15,18-22,29,30,34,36,40 and 51-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,14,15,18-22,29,30,34,36,40 and 51-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/4/06, 8/7/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 9/1/06.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 3,4,14,15,18-22,29,30 34,36,40 and 51-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Notenbomber (EP 0 730 494 hereafter '494) in view of Kelly (US 2003/0065090 hereafter '090). The claims are drawn to a particle composition comprising a core and coating, wherein the core comprises a cation exchange resin and the coating is permeable to potassium ions. The coating has a thickness from 0.002-50 microns.

4. The '494 patent discloses a particle formulation comprising a core and a coating where the core comprises a cation exchange resin and the coating is permeable to potassium ions (page 1, lin. 49-55). The particles are safe means of absorbing cations from the human body, encapsulating the ions and removing them through the GI tract with feces (page 2, lines 8-12).

Art Unit: 1618

The cation exchange materials come from a wide range of sources and can include sulphonated crosslinked polystyrenes (page 2, lin. 20-34). The coating comprises crosslinked polyphosphate polymers, yet is silent to the specific monomers of the instant claims. The particles have an average size of 290 microns (Example 1). The thickness of the coating can be adjusted in the granulation process and it dependent on the desired ion needed for entrapment.

5. The reference is silent to the specific monomers recited in the instant claims. However these monomers are common the art and can be found in use in the '090 application.

6. The '090 application discloses a core/shell particle comprising a cationic exchange resin in the core and a crosslinked polymer coating (abstract). The polymer coating comprises polyaniline along with crosslinked vinyl, acrylic and methacrylic monomers [0033-0035]. The mixture creates a polymer matrix that surrounds the core as a shell with a thickness of 25.4 microns [0030]. A skilled artisan would be motivated to include these crosslinking monomers of the '090 in order to provide stability to the coated microparticles.

7. Regarding the affinity of the cation exchange polymer and permeability of the coating, as seen in the '494 these factors can be adjusted to bind any number of mono or bi-valent cations such as K^+ , H^+ , NH_4 and Na^+ . The formulation can be modified to absorb the desired cation in the GI tract by applying various ions to the surface of the particle or by changing the cation exchange resin, all of which is well within the level of skill in the art. These binding can be determined through routine experimentation in the art.

8. Regarding the treatment of various renal disorders it is the position of the Examiner that these limitations are merely a future intended use for the disclosed product. Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a

Art Unit: 1618

purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). The treatment of the various renal disorders comprises merely administering the formulation comprising the cation exchange resin coating with a crosslinked polymer. The formulation treats these disorders by binding potassium ions which is accomplished by the '494 patent. The ions are bound by the particles and excreted after not disintegrating in the GI tract. Applicant is reminded that a compound and its properties cannot be separated. It is the position of the Examiner that the potassium binding particles of the '494 would inherently treat various renal disorders. For these reasons it would be prima facie obvious to use the potassium binding particles of the '494 in methods of treating renal disorders.

9. Regarding the ratios of the shell to the core, it is the position of the Examiner that these limitations do not impart patentability on the claims. Since the thickness and concentration of polymers can be modified during the coating process, it is the position of the Examiner that these ratios can be determined through routine experimentation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

10. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not

Art Unit: 1618

patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

11. Further regarding polymerization of the polymer coating, it is the position of the Examiner that such limitations do not impart patentability since they render the claims product-by process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

12. With these things in mind it would have been obvious to combine the specific monomers of the ‘090 application into the coating of the ‘494 in order to increase the stability of the coating and particle formulation. An artisan would have further been motivated to combine the thin coating to the core in order to promote the binding of the potassium ions. An artisan of ordinary skill also would have been motivated to treat patient suffering from renal disorders since potassium binding is required and the particles of the combination would inherently bind potassium ions. One of ordinary skill in the art would have been motivated to combine the teachings and suggestions in the art with an expected result of a stable potassium-binding particle useful in treating various renal disorders.

Response to Arguments

13. Applicant's arguments with respect to claims 3,4,14,15,18-22,29,30,34,36,40,51-75 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

1. Claims 3,4,14,15,18-22,29,30,34,36,40, and 51-75 of this application conflict with claims 1,10,16,17,20-24,31,32,45-65 of Applicant No. 10/813,872. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

2. Claims 3,4,14,15,18-22,29,30,34,36,40, and 51-75 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,10,16,17,20-24,31,32,45-65 of copending Application No. 10/813,872. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims recite pharmaceutical formulations comprising core-shell formulation comprising potassium-binding polymers that are crosslinked. The formulations both have shells with thicknesses up to 50 microns. These claims would act as obviating art over each other.

3. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1618

Correspondence

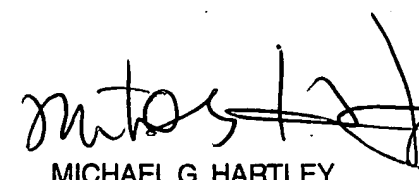
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618


MP Young


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER